REMARKS

STATUS OF CLAIMS

Claims 1-39 are pending. Claims 4, 8, 10 and 17 have been amended to recite the ATCC accession numbers. No new matter has been added by virtue of these claim amendments.

Applicants attach an annotated version of the claims indicating amendments as Exhibit A. Applicants attach an annotated version of the amended pages 19-25, and 27 of the specification indicating amendments as Exhibit B. No new matter has been added by virtue of these amendments. A copy of the deposit receipt from the American Type Culture Collection is enclosed as Exhibit C

SPECIFICATION

As required by 37 C.F.R. § 1.821(d) the specification of the present application has been amended to the correct format for the "SEQ ID NO:" identifier. Specifically, --SEQ ID NO: 1-- has been inserted in place of "SEQ ID:1" on page 19, line 22, "SEQ ID 1" on page 22, line 14, and "SEQ. ID: 1" on page 22, lines 20-21.

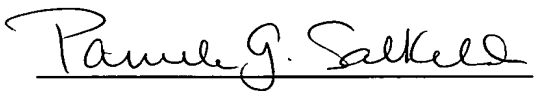
As required by 37 C.F.R. § 1.809(d) the specification of the present application has been amended to refer to the address of the depository. Applicants noted that the address for the ATCC originally cited was out of date. Specifically, the current address of the American Type Culture Collection has been inserted on page 20, lines 3-4, page 20, lines 27-28, page 21, lines 14-15, page 24, lines 3-4, page 25, lines 27-28 and page 27, lines 25-26 in place of the former address that was originally cited.

The specification has been amended to correct the sequence identifier used at page 23, line 9 from "SEQ ID 2" and at page 23, lines 14-15 from"SEQ. ID: 2" to --SEQ ID NO: 3--. In support for this amendment, Applicants point out that the MPEP

2163.07, section II states that "an amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also the appropriate correction." This Amendment does not constitute new matter because it would be obvious to one of skill in the art that the correct reference is to the DNA sequence of SEQ ID NO: 3 rather than the protein sequence of SEQ ID NO: 2.

As required by 37 C.F.R. § 1.809(d) the specification of the present application has been amended to refer to the accession numbers and dates for biological deposits. Applicants have amended the descriptions of the biological deposits on page 24, line 4, page 25, line 28 and page 27, line 26 of the specification because the accession numbers were unknown to the Applicants at the time of filing.

Respectfully submitted,



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PGS:nvc
19250_1

EXHIBIT A- Version with Markings to Show Changes Made

4. (Amended) The recombinant avian herpesvirus of claim 3 designated NAHV/NDV 295-93 (ATCC Accession number [VR_____] PTA-3453).

8. (Amended) The recombinant avian herpesvirus of claim 7 designated NAHV/ILT 295-149 (ATCC Accession number [VR_____] PTA-3452).

10. (Amended) The recombinant avian herpesvirus designated NAHV 295-01 (ATCC Accession number [VR_____] PTA-3451).

17. (Amended) A multivalent vaccine for protecting against Marek's disease, infectious laryngotracheitis and Newcastle disease comprising, as a mixture, an effective immunizing amount of a first recombinant avian herpesvirus, designated NAHV/ILT 295-149 (ATCC Accession number [VR_____]PTA-3452), an effective immunizing amount of a second recombinant avian herpesvirus, designated NAHV/NDV 295-93 (ATCC Accession number [VR_____]PTA-3453), and a suitable carrier.

EXHIBIT B- Version with Markings to Show Changes Made

The dC-tailed DNA sample was annealed to 200 ng plasmid vector pBR322 that contained oligo-dG tails (Bethesda Research Labs #5355 SA/SB) in 200 µl of 0.01 M Tris pH 7.5, 0.1 M NaCl, 1 mM EDTA pH 8.0 at 65°C for 2 min and then 57°C for 2 hrs. Fresh competent *E. coli* DH-1 cells were prepared and transformed as described by Hanahan (*Molecular Biology* **166**, 557-580, 1983) using half the annealed cDNA sample in twenty 200 µl aliquots of cells. Transformed cells were plated on L-broth agar plates plus 10 µg/ml tetracycline. Colonies were screened for the presence of inserts into the ampicillin gene using Ampscreen (Bethesda Research Labs #5537 UA), and the positive colonies were picked for analysis. Resulting positive clones were screened for homology to paramyxovirus fusion gene sequences. A clone containing the complete coding sequence of the NDV fusion gene was identified. The sequence of this clone is given in [SEQ ID: 1] SEQ ID NO: 1.

Subgenomic Clone 407-32.2C3

Cosmid 407-32.2C3 contains an approximately 40,000 base pair region of genomic HVT DNA (from the left terminus to position 39,750 GenBank Accession No. AF291866, see figure 2). This region includes NAHV *Bam*HI fragments F', L, P, N1, E, D, and 2,092 base pairs of fragment A'. Note: NAHV *Bam*HI fragment A', is called fragment B in HVT. This cosmid may be constructed as described above in the Procedure for Cloning NAHV Subgenomic DNA Fragments. It was isolated from the sheared DNA library by screening with the probes P1 (HVT *Bam*HI fragment F, position 116,948 to 125,961, Genbank Accession No. AF291866) and P2 (HVT *Bam*HI fragment B, 37,663 to 63,593, Genbank Accession No. AF291866). A bacterial strain containing

this cosmid has been deposited pursuant to the Budapest Treaty on the International Deposit of Microorganisms for the Purposes of Patent Procedure with the Patent Culture Depository of the American Type Culture Collection, [12301 Parklawn Drive, Rockville, Maryland 20852] 10801 University Boulevard, Manassas, Virginia, 20010-2209 U.S.A. under ATCC Accession No. 75430.

Cosmid 407-32.5G6 contains a 39,404 base pair region of genomic HVT DNA (position 61,852 to 101,255, Genbank Accession No. AF291866). This region includes NAHV *Bam*HI fragments H, C, Q, K1, M, K2, plus 1,742 base pairs of fragment A', and 3,880 base pairs of fragment J. Note: NAHV *Bam*HI fragment A', is called fragment B in HVT. This cosmid was constructed as described above in the Procedure for Cloning NAHV Subgenomic DNA Fragments. It was isolated from the sheared DNA library by screening with the probes P2 (HVT *Bam*HI fragment B, 37,663 to 63,593, Genbank Accession No. AF291866) and P3 (HVT *Bam*HI fragment J, position 97,376 to 102,720, Genbank Accession No. AF291866). A bacterial strain containing this cosmid has been deposited on March 3, 1993 pursuant to the Budapest Treaty on the International Deposit of Microorganisms for the Purposes of Patent Procedure with the Patent Culture Depository of the American Type Culture Collection, [12301 Parklawn Drive, Rockville, Maryland 20852] 10801 University Boulevard, Manassas, Virginia, 20010-2209 U.S.A. under ATCC Accession No. 75427.

Subgenomic Clone 407-32.1C1

Cosmid 407-32.1C1 contains a 37,444 base pair region of genomic HVT DNA (position 96,095 to 133,538, GenBank Accession No. AF291866, see figure 2). This region includes NAHV *Bam*HI fragments J, G, I, F, O, plus 1,281 base pairs of fragment

K2, and 6,691 base pairs of fragment B'. Note: NAHV *Bam*HI fragment B', is called fragment A in HVT. This cosmid was constructed as described above in the Procedure for Cloning NAHV Subgenomic DNA Fragments. It was isolated from the sheared DNA library by screening with the probes P1 (HVT *Bam*HI fragment F, position 116,948 to 125,961, Genbank Accession No. AF291866) and P4 (4169 base pair *Bgl*II to *Stu*I sub-fragment (position 132,088 to 136,256, GenBank Accession No. AF291866) of HVT *Xho*I fragment #5 (position 128,950 to 136,510, GenBank Accession No. AF291866)). Note: an internal *Stu*I site occurs within the 4169 base pair sub-fragment (position 134,083, GenBank Accession No. AF291866). However this site is methylated and does not cleave in plasmid DNA prepared from standard cloning strains of bacteria. A bacterial strain containing this cosmid has been deposited on March 3, 1993 pursuant to the Budapest Treaty on the International Deposit of Microorganisms for the Purposes of Patent Procedure with the Patent Culture Depository of the American Type Culture Collection, [12301 Parklawn Drive, Rockville, Maryland 20852] 10801 University Boulevard, Manassas, Virginia, 20010-2209 U.S.A. under ATCC Accession No. 75428.

EXHIBIT B- Version with Markings to Show Changes Made

The cosmid 1002-75.4 contains a foreign gene encoding the fusion protein of the Newcastle disease virus inserted within the MDV US2 gene of the NAHV short region cosmid, 989-72.8#1. The NDV fusion gene (F) is under the control of the human cytomegalovirus immediate early (HCMV IE) promoter and utilizes the herpes simplex virus thymidine kinase (HSV tk) poly adenylation signal (pA). This cosmid was created using standard DNA cloning techniques. The sequence of the foreign DNA inserted into cosmid 989-72.8#1 is given in [SEQ ID 1] SEQ ID NO: 1. This sequence was inserted such that the NDV F and MDV US2 genes are transcribed in the same direction. The source of each region of the insert is indicated in the following table.

[a] Starting position of the region in [SEQ. ID: 1] SEQ ID NO: 1

[b] Ending position of the region in [SEQ. ID: 1] SEQ ID NO: 1

EXHIBIT B- Version with Markings to Show Changes Made

The cosmid 1012-89.2 contains two foreign genes encoding the glycoprotein D and glycoprotein I of the infectious laryngotracheitis virus (ILTV) inserted in to the MDV US2 gene of the NAHV short region cosmid, 989-72.8#1. The ILTV genes are under the control of their endogenous promoters. This cosmid was created using standard DNA cloning techniques. The sequence of the foreign DNA inserted into cosmid 989-72.8#1 is given in [SEQ ID 2] SEQ ID NO:3. This sequence was inserted such that the ILTV gD gene and ILTV gI gene are transcribed in the opposite direction of the MDV US2 genes. The source of each region of the insert is indicated in the following table.

[a] Starting position of the region in [SEQ. ID: 2] SEQ ID NO: 3

[b] Ending position of the region in [SEQ. ID: 2] SEQ ID NO: 3

The NAHV 295-01 recombinant virus was generated according to the Procedure for Generating Novel Avian Herpesvirus from Overlapping Subgenomic Fragments. The following combination of subgenomic clones and enzymes were used: 989-72.8#1 with I-*Sce*I, 407-32.2C3 with *Not*I, 172-07.BA2 with *Bam*HI, 407-32.5G6 with *Not*I, and 407-32.1C1 with *Not*I. (The location of subgenomic clones on the resulting NAHV genome is indicated in figure 2.) The NAHV was shown to have the correct genomic structure using the Southern Blot Analysis of Novel Avian Herpesviruses. Stability of the NAHV 295-01 virus vaccine strain was demonstrated by serial passage 12 times in tissue culture followed by a second Southern blot analysis. This virus strain has been deposited

EXHIBIT B- Version with Markings to Show Changes Made

pursuant to the Budapest Treaty on the International Deposit of Microorganisms for the Purposes of Patent Procedure with the Patent Culture Depository of the American Type Culture Collection, [12301 Parklawn Drive, Rockville, Maryland 20852] 10801 University Boulevard, Manassas, Virginia, 20010-2209 U.S.A. under ATCC Accession No. [_____] PTA-3451 on June 13, 2001.

EXHIBIT B- Version with Markings to Show Changes Made

The NAHV/NDV 295-93 recombinant virus was generated according to the Procedure for Generating Novel Avian Herpesvirus from Overlapping Subgenomic Fragments. The following combination of subgenomic clones and enzymes were used: 1002-75.4 with I-*Sce*I, 407-32.2C3 with *Not*I, 172-07.BA2 with *Bam*HI, 407-32.5G6 with *Not*I, and 407-32.1C1 with *Not*I. (The location of subgenomic clones on the resulting NAHV genome is indicated in figure 2.) The NAHV was shown to have the correct genomic structure using the Southern Blot Analysis of Novel Avian Herpesviruses. Stability of the NAHV/NDV 295-93 virus vaccine strain was demonstrated by serial passage 12 times in tissue culture followed by a second Southern blot analysis. This virus strain has been deposited pursuant to the Budapest Treaty on the International Deposit of Microorganisms for the Purposes of Patent Procedure with the Patent Culture Depository of the American Type Culture Collection, [12301 Parklawn Drive, Rockville, Maryland 20852] 10801 University Boulevard, Manassas, Virginia, 20010-2209 U.S.A. under ATCC Accession No. [ ] PTA-3453 on June 13, 2001.

EXHIBIT B- Version with Markings to Show Changes Made

The NAHV/ILT 295-149 recombinant virus was generated according to the Procedure for Generating Novel Avian Herpesvirus from Overlapping Subgenomic Fragments. The following combination of subgenomic clones and enzymes were used: 1012-89.2 with I-*Sce*I, 407-32.2C3 with *Not*I, 172-07.BA2 with *Bam*HI, 407-32.5G6 with *Not*I, and 407-32.1C1 with *Not*I. (The location of subgenomic clones on the resulting NAHV genome is indicated in figure 2.) The NAHV was shown to have the correct genomic structure using the Southern Blot Analysis of Novel Avian Herpesviruses. Stability of the the NAHV/ILT 295-149 virus vaccine strain was demonstrated by serial passage 12 times in tissue culture followed by a second Southern blot analysis. This virus strain has been deposited pursuant to the Budapest Treaty on the International Deposit of Microorganisms for the Purposes of Patent Procedure with the Patent Culture Depository of the American Type Culture Collection, [12301 Parklawn

EXHIBIT B- Version with Markings to Show Changes Made

Drive, Rockville, Maryland 20852] 10801 University Boulevard, Manassas, Virginia, 20010-2209U.S.A. under ATCC Accession No.[_____] PTA-3452 on June 13, 2001.

ATCC

EXHIBIT C

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Schering-Plough Corporation
Patent Department K-6-1 1800
Attn: Pamela G. Salkeld
2000 Galloping Hill Road
Kenilworth, NJ 07033

Deposited on Behalf of: Schering-Plough Corporation

Identification Reference by Depositor:	**Patent Deposit Designation**
Novel avian herpesvirus (NAHV) infected chicken embryo fibroblast cells: NAHV 295-01	PTA-3451
Novel avian herpesvirus (NAHV) infected chicken embryo fibroblast cells: NAHV/ILT 295-149	PTA-3452
Novel avian herpesvirus (NAHV) infected chicken embryo fibroblast cells: NAHV/NDV 295-93	PTA-3453
(Ref: Docket or Case No.: SY01105K1QKQK)	

The deposits were accompanied by: ___ a scientific description _ a proposed taxonomic description indicated above. The deposits were received June 13, 2001 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested August 13, 2001. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Tanya Nunnally, Patent Specialist, Patent Depository

Date: September 4, 2001